REMARKS

I. Pending claims

Claims 21-40 are pending in the above-captioned application. Claims 21-40 are newly added. Claims 1-20 have been cancelled.

Newly added claims 21-40 correspond to originally filed claims 1-20, and are directed to similar subject matter. Specifically, newly added claims 22, 24, 25, 27, 29, 30, 32, and 33 correspond to originally filed claims, 2, 3, 13, 12, 4, 5, 6, and 7, respectively, which were placed by the Examiner in Group II. Accordingly, these, as well as newly added claims 31, 34, and 35, drawn to antibodies to SEQ ID NO:1, and methods of preparing said antibodies, should be examined together with the claims of Group II.

Newly added claims 23 and 37 are directed to the same subject matter as originally filed claims 9, 10, and 11, which were placed by the Examiner in Group IV. Accordingly, newly added claims 23 and 37, drawn to methods of using the claimed antibodies to detect expression of a protein in a sample, should be examined together with the claims of Group IV.

Newly added claim 38 corresponds to original claim 8, which was placed by the Examiner in Group III. Newly added claim 26 is directed to the same subject matter as originally filed claims 15 and 16, which were placed by the Examiner in Groups V and VI, respectively. Newly added claims 39-40 correspond to originally filed claims 17 and 19, which were placed by the Examiner in Groups VII and IX, respectively.

Newly added claim 28 is drawn to a method of using the claimed antibodies. In addition, newly added claim 36 is drawn to the antibody of claim 22, wherein the antibody is produced by screening a recombinant immunoglobulin library, and corresponds in scope with original claim 3, and thus should be considered with the claims of Group II.

Support for the newly added claims may be found in the Application as filed. Applicants expressly do not disclaim the subject matter of any invention disclosed herein which is not set forth in the instantly filed claims. Applicants reserve the right to prosecute the non-elected claims in subsequent divisional applications. No new matter is added by any of these amendments.

Group Number	Original Claims	New Claims
Group I, drawn to a human prostate-associated protease.	1	21
Group II, drawn to an antibody against human prostate-associated protease and methods of preparing said antibody.	2	22
	3	24
	4	29
	5	30, 31
	6	32
	7	33, 34
	12	27
	13	25
Group III, drawn to a method for using an antibody to immunopurify a protein.	8	38
Group IV, drawn to drawn to a method for using an antibody to detect expression of a protein in a sample.	9	37
	10	23
	11	23
Group V, drawn to a method for using an antibody to treat a prostatic disorder.	15	26
Group VI, drawn to a method for using an antibody to treat a gastrointestinal disorder.	16	26
Group VII, drawn to a method for testing a molecule or compound for effectiveness as an agonist for the human prostate-associated protease.	17	39
Group IX, drawn to a method for testing a molecule or compound for effectiveness as an antagonist for the human prostate-associated protease.	19	40
Method of diagnosing a condition or disease associated with the expression of HUPAP in a subject, comprising administering to said subject an effective amount of the composition of claim 27.		28
The antibody of claim 22, wherein the antibody is produced by screening a recombinant immunoglobulin library.		35

II. Restriction Requirement

In the Restriction Requirement, the Examiner requested Applicants to elect one of the following inventions:

Group I (claim 1) drawn to a human prostate-associated protease,

Group II (claims 2-7 and 12-14) drawn to an antibody against human prostate-associated protease and methods of preparing said antibody,

Group III (claim 8) drawn to a method for using an antibody to immunopurify a protein,

Group IV (claims 9-11) drawn to drawn to a method for using an antibody to detect expression of a protein in a sample,

Group V (claim 15) drawn to a method for using an antibody to treat a prostatic disorder,

Group VI (claim 16) drawn to a method for using an antibody to treat a gastrointestinal disorder,

Group VII (claim 17) drawn to a method for testing a molecule or compound for effectiveness as an agonist for the human prostate-associated protease,

Group VIII (claim 18) drawn to an agonist for the human prostate-associated protease,

Group IX (claim 19) drawn to a method for testing a molecule or compound for effectiveness as an antagonist for the human prostate-associated protease,

Group X (claim 20) drawn to an antagonist for the human prostate-associated protease.

Applicants hereby elect, **with traverse**, to prosecute Group II, drawn to antibodies to SEQ ID NO:1, human prostate-associated protease, and methods of preparing said antibodies. Applicants reserve the right to prosecute the subject matter of non-elected claims in subsequent divisional applications. Applicants traverse the Restriction Requirement for at least the following reasons.

Applicants respectfully submit that there is minimal burden on the Examiner to examine claims 8-11 (Groups III-VII), drawn to methods of using antibodies to SEQ ID NO:1. The method claims of Groups III-VII recite a product (i.e., an antibody), which is of the same scope as the claimed antibodies being searched by the Examiner. Thus, it would pose no undue burden on the Examiner to examine these method claims since a search of the

prior art to determine the novelty of the claimed antibodies would substantially overlap with a search of the prior art to determine the novelty of the method claims.

Moreover, upon allowance of the claims in Group II, claims 22, 24, 25, 29, 30, and 32-35, claims 23, 26, 27, 31 and 37-38, should be rejoined and considered, in accordance with the Commissioner's Notice in the Official Gazette of March 26, 1996, entitled "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)" which sets forth the rules, upon allowance of product claims, for rejoinder of process claims covering the same scope of products. Accordingly, the method claims of newly added claims 23, 26, 27, 31, and 37-38 should be considered with the product claims from which they depend, claims 22, 24, 25, 29, 30, and 32-35. See also M.P.E.P. 821.04 as follows:

> Where product and process claims drawn to independent and distinct inventions are presented in the same application, applicant may be called upon under 35 U.S.C. 121 to elect claims to either the product or process. . . The claims to the nonelected invention will be withdrawn from further consideration under 37 C.F.R. 1.142. . . . However, if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined.

Further, Applicants respectfully submit that there is minimal additional burden on the Examiner to examine claim 21, drawn to polypeptides, since claims directed to "polypeptide inventions" have already been issued in the parent case, which is now U.S. Patent No. 6,350,448. For the Examiner's convenience, the issued claims are reproduced below. Upon allowance of claim 21, claims 39 and 40, directed to methods of using the polypeptides of claim 21, should be rejoined for the reasons given above. Thus, Applicants request reconsideration and withdrawal of the Restriction Requirement and examination of the entirety Applicants' claims.

U.S. Patent No. 6,350,448:

1. A purified human prostate-associated protease comprising a protein having the amino acid sequence of SEQ ID NO:1.

2. A composition comprising the protein of claim 1 and a pharmaceutical carrier.

3. A composition comprising the protein of claim 1 and a reporter molecule.

4. A fusion protein comprising a heterologous protein sequence and the protein of claim 1.

5. An antigenic fragment consisting of Cys22-Ser 45 of SEQ ID NO:1.

6. A composition comprising the fragment of claim 5 and a reporter molecule.

7. A fusion protein comprising a heterologous protein sequence and the fragment of claim 5.

8. A method for treating a gastrointestinal disorder comprising administering to a subject in need of such treatment the composition of claim 2.

9. A method for using a protein to screen a library of molecules or compounds to identify at least one molecule or compound which specifically binds the protein, the method comprising:

a) combining the protein of claim 1 with the library of molecules or compounds under conditions to allow specific binding; and

b) detecting specific binding, thereby identifying a molecule or compound which specifically binds the protein.

10. The method of claim 9 wherein the library is selected from peptides, agonists, antagonists, antibodies, immunoglobulins, inhibitors, drug compounds, and pharmaceutical agents.

11. A method of using a protein to purify a molecule or compound which specifically binds the protein from a sample, the method comprising:

a) combining the protein of claim 1 with the sample under conditions to allow specific binding;

b) recovering the bound protein; and

d) separating the protein from the molecule or compound, thereby obtaining the purified molecule or compound.

Applicants believe that no fee is due with this communication. However, if the USPTO determines that a fee is due, the Commissioner is hereby authorized to charge Deposit Account No. 09-0108.

Respectfully submitted,
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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

Claims 1-20 have been canceled.

Claims 21-40 have been added.

21. (New) An isolated polypeptide selected from the group consisting of:

a) a polypeptide comprising the amino acid sequence of SEQ ID NO:1,

b) a polypeptide comprising a naturally occurring amino acid sequence at least 90% identical to the amino acid sequence of SEQ ID NO:1,

c) a fragment of a polypeptide having the amino acid sequence of SEQ ID NO:1, wherein said fragment binds to microtubules and

d) an immunogenic fragment of a polypeptide having the amino acid sequence of SEQ ID NO:1.

22. (New) An isolated antibody which specifically binds to an isolated polypeptide selected from the group consisting of:

a) a polypeptide comprising the amino acid sequence of SEQ ID NO:1,

b) a polypeptide comprising a naturally occurring amino acid sequence at least 90% identical to the amino acid sequence of SEQ ID NO:1,

c) a fragment of a polypeptide having the amino acid sequence of SEQ ID NO:1, wherein said fragment binds to microtubules and

d) an immunogenic fragment of a polypeptide having the amino acid sequence of SEQ ID NO:1.

23. (New) A method for a diagnostic test for a condition or disease associated with the expression of HUPAP in a biological sample, the method comprising:

a) combining the biological sample with an antibody of claim 22, under conditions suitable for the antibody to bind the polypeptide and form an antibody:polypeptide complex, and

b) detecting the complex, wherein the presence of the complex correlates with the presence of the polypeptide in the biological sample.

24. (New) The antibody of claim 22, wherein the antibody is:

a) a chimeric antibody,

b) a single chain antibody,

c) a Fab fragment,

d) a $F(ab')_2$ fragment, or

e) a humanized antibody.

25. (New) A composition comprising an antibody of claim 22 and an acceptable excipient.

26. (New) A method of diagnosing a condition or disease associated with the expression of HUPAP in a subject, comprising administering to said subject an effective amount of the composition of claim 24.

27. (New) A composition of claim 24, further comprising a label.

28. (New) A method of diagnosing a condition or disease associated with the expression of HUPAP in a subject, comprising administering to said subject an effective amount of the composition of claim 26.

29. (New) A method of preparing a polyclonal antibody with the specificity of the antibody of claim 22 comprising:

a) immunizing an animal with a polypeptide having the amino acid sequence of SEQ ID NO:1, or an immunogenic fragment thereof, under conditions to elicit an antibody response;

b) isolating antibodies from said animal; and

c) screening the isolated antibodies with the polypeptide, thereby identifying a polyclonal antibody which binds specifically to a polypeptide having the amino acid sequence of SEQ ID NO:1.

30. (New) a polyclonal antibody produced by a method of claim 29.

31. (New) A composition comprising the antibody of claim 30 and a suitable carrier.

32. (New) A method of making a monoclonal antibody with the specificity of the antibody of claim 22 comprising:

a) immunizing an animal with a polypeptide having the amino acid sequence of SEQ ID NO:1, or an immunogenic fragment thereof, under conditions to elicit an antibody response;

b) isolating antibody producing cells from the animal;

c) fusing the antibody producing cells with immortalized cells to form monoclonal antibody-producing hybridoma cells;

d) culturing the hybridoma cells; and

e) isolating from the culture monoclonal antibody which binds specifically to a polypeptide having the amino acid sequence of SEQ ID NO:1.

33. (New) A monoclonal antibody produced by a method of claim 32.

34. (New) A composition comprising the antibody of claim 33 and a suitable carrier.

35. (New) The antibody of claim 22, wherein the antibody is produced by screening a Fab expression library.

36. (New) The antibody of claim 22, wherein the antibody is produced by screening a recombinant immunoglobulin library.

37. (New) A method for detecting a polypeptide having the amino acid sequence of SEQ ID NO:1 in a sample, comprising the steps of:

a) incubating the antibody of claim 22 with a sample under conditions to allow specific binding of the antibody and the polypeptide; and

b) detecting specific binding, wherein specific binding indicates the presence of a polypeptide having the amino acid sequence of SEQ ID NO:1 in the sample.

38. (New) A method of purifying a polypeptide having the amino acid sequence of SEQ ID NO:1 from a sample, the method comprising:

a) incubating the antibody of claim 22 with a sample under conditions to allow specific binding of the antibody and the polypeptide; and

b) separating the antibody from the sample and obtaining the purified polypeptide having the amino acid sequence of SEQ ID NO:1.

39. (New) A method of screening a compound for effectiveness as an agonist of a polypeptide of claim 21, the method comprising:

a) contacting a sample comprising a polypeptide of claim 21 with a compound, and

b) detecting agonist activity in the sample.

40. (New) A method of screening a compound for effectiveness as an antagonist of a polypeptide of claim 21, the method comprising:

a) contacting a sample comprising a polypeptide of claim 21 with a compound, and

b) detecting antagonist activity in the sample.